

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PAR PHARMACEUTICAL, INC., and ENDO)
PAR INNOVATION COMPANY, LLC,)
Plaintiffs,)
v.) C.A. No. 23-866-RGA-LDH
ZYDUS PHARMACEUTICALS (USA) INC.)
and ZYDUS LIFESCIENCES LTD.,)
Defendants.)

SCHEDULING ORDER

This 6 day of November, 2023, the Court having waived an initial Rule 16(b) scheduling conference pursuant to Local Rule 16.1(b), and the parties having determined after discussion that the matter cannot be resolved at this juncture by settlement, voluntary mediation, or binding arbitration;

IT IS ORDERED that:

1. Rule 26(a)(1) Initial Disclosures. Unless otherwise agreed to by the parties, the parties shall make their initial disclosures pursuant to Federal Rule of Civil Procedure 26(a)(1) within five days of the date of this Order.

2. Joinder of Other Parties and Amendment of Pleadings. All motions to join other parties, and to amend or supplement the pleadings, shall be filed on or before March 20, 2024.

3. Discovery.

a. Disclosures

i. By November 20, 2023, Plaintiffs shall identify the accused product(s), including accused methods and systems, as well as the asserted patent(s) that the

accused product(s) allegedly infringe(s). Plaintiffs shall also produce the file history for each asserted patent.

ii. By December 7, 2023, both parties shall provide initial discovery disclosures provided for in Paragraph 3 of the District of Delaware Default Standard for Discovery, Including Discovery of Electronically Stored Information (“ESI”).

iii. By December 20, 2023, Plaintiffs shall produce an initial claim chart relating each known accused product to the asserted claims each such product allegedly infringes.

iv. By January 26, 2024, Defendants shall produce their initial invalidity contentions for each asserted claim, as well as the known related invalidating references.

v. By June 14, 2024, absent agreement among the parties, and approval of the Court, the parties must finally supplement, *inter alia*, the identification of all accused products and of all invalidity references.

vi. By June 24, 2024, Plaintiffs shall provide final infringement contentions and asserted claims.

vii. By July 2, 2024, Defendants shall provide final invalidity contentions.

b. Discovery Cut Off. All fact discovery in this case shall be initiated so that it will be completed on or before July 16, 2024.

c. Document Production. Document production shall be substantially complete by March 28, 2024.

d. Requests for Admission. A maximum of 50 requests for admission are permitted for each side, not including requests related to authentication of documents.

e. Interrogatories. A maximum of 25 interrogatories, including contention interrogatories, are permitted for each side.

f. Depositions.

i. Limitation on Hours for Deposition Discovery. Each side is limited to a total of 70 hours of taking testimony by deposition upon oral examination (excluding depositions of expert witnesses).

ii. Location of Depositions. Any party or representative (officer, director, or managing agent) of a party filing a civil action in this district court must ordinarily be required, upon request, to submit to a deposition at a place designated within this district. Exceptions to this general rule may be made by order of the Court or by agreement of the parties. A defendant who becomes a cross-claimant or third-party plaintiff shall be considered as having filed an action in this Court for the purpose of this provision.

g. Discovery Matters and Disputes Relating to Protective Orders. Should counsel find they are unable to resolve a discovery matter or a dispute relating to a protective order, the parties involved in the discovery matter or protective order dispute shall contact the Court's Case Manager to schedule an in-person conference/argument. Unless otherwise ordered, by no later than seven business days prior to the conference/argument, any party seeking relief shall file with the Court a letter, not to exceed three pages, outlining the issues in dispute and its position on those issues. By no later than five business days prior to the conference/argument, any party opposing the application for relief may file a letter, not to exceed three pages, outlining that party's opposition. A party should include with its letter a proposed order with a detailed issue-by-issue ruling such that, should the Court agree with the party on a particular issue, the Court could sign the proposed order as to that issue, and the opposing party would be able to understand what it

needs to do, and by when, to comply with the Court's order. Any proposed order shall be e-mailed, in Word format, simultaneously with filing to rga_civil@ded.uscourts.gov.

If a discovery-related motion is filed without leave of the Court, it will be denied without prejudice to the moving party's right to bring the dispute to the Court through the discovery matters procedures set forth in this Order.

h. The patent in suit is the subject of two pending lawsuits in the Eastern District of Texas: *Par Pharmaceutical, Inc., et al. v. Mankind Pharma Ltd.*, C.A. No. 2:23-cv-399, and *Par Pharmaceutical, Inc., et al. v. Alkem Laboratories, Ltd.*, C.A. No. 2:23-cv-400. Par may institute one or more additional lawsuits against other varenicline tartrate manufacturers in within the next year. Defendants have not decided whether they expect to file any inter partes reviews and, if so, when.

4. Application to Court for Protective Order. Should counsel find it will be necessary to apply to the Court for a protective order specifying terms and conditions for the disclosure of confidential information, counsel should confer and attempt to reach an agreement on a proposed form of order and submit it to the Court within five days from the date of this Order. Should counsel be unable to reach an agreement on a proposed form of order, counsel must follow the provisions of Paragraph 3(g) above.

Any proposed protective order must include the following paragraph:

Other Proceedings. By entering this order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this order who becomes subject to a motion to disclose another party's information designated as confidential pursuant to this order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

5. Papers Filed Under Seal. When filing papers under seal, a redacted version of any sealed document shall be filed electronically within seven days of the filing of the sealed document.

6. Claim Construction Issue Identification. On or before February 6, 2024, the parties shall exchange a list of those claim term(s)/phrase(s) that they believe need construction and their proposed claim construction of those term(s)/phrase(s)¹. This document will not be filed with the Court. Subsequent to exchanging that list, the parties will meet and confer to prepare a Joint Claim Construction Chart to be filed no later than February 20, 2024. The Joint Claim Construction Chart, in Word format, shall be e-mailed simultaneously with filing to rga_civil@ded.uscourts.gov. The Joint Claim Construction Chart should identify for the Court the term(s)/phrase(s) of the claim(s) in issue, and should include each party's proposed construction of the disputed claim language with citation(s) only to the intrinsic evidence in support of their respective proposed constructions. The Joint Claim Construction Chart should include an explanation of why resolution of the dispute makes a difference. A copy of the patent(s) in issue as well as those portions of the intrinsic record relied upon shall be submitted with the Joint Claim Construction Chart. In this joint submission, the parties shall not provide argument.

7. Claim Construction Briefing². Plaintiff shall serve, but not file, its opening brief, not to exceed 5,000 words, on March 22, 2024. Defendant shall serve, but not file, its answering

¹ If a party proposes a construction of a term to be its “plain and ordinary” meaning, the party must explain what that meaning is. If a term is arguably a means-plus-function term, and a party does not propose a function and a structure, it is waiving any right to propose a function and a structure at a later time.

² As each brief is written and provided to the opposing party, the individual responsible for verifying the word count will represent to the other party that it has so verified and by what means. These verifications should not be provided to the Court unless a dispute arises about them. Pictures, figures copied from the patent, and other illustrations do not count against the word limit. Plaintiff should include with its opening brief one or more representative claims with the disputed terms italicized. Should Defendant want to add additional representative claims, Defendant may do so.

brief, not to exceed 7,500 words, on April 23, 2024. Plaintiff shall serve, but not file, its reply brief, not to exceed 5,000 words, on May 7, 2024. Defendant shall serve, but not file its sur-reply brief, not to exceed 2,500 words, on May 21, 2024. No later than May 28, 2024, the parties shall file a Joint Claim Construction Brief. The parties shall copy and paste their unfiled briefs into one brief, with their positions on each claim term in sequential order, in substantially the form below.

JOINT CLAIM CONSTRUCTION BRIEF

- I. Representative Claims
- II. Agreed-upon Constructions
- III. Disputed Constructions
 - A. [TERM 1]
 - 1. Plaintiff's Opening Position
 - 2. Defendant's Answering Position
 - 3. Plaintiff's Reply Position
 - 4. Defendant's Sur-Reply Position
 - B. [TERM 2]
 - 1. Plaintiff's Opening Position
 - 2. Defendant's Answering Position
 - 3. Plaintiff's Reply Position
 - 4. Defendant's Sur-Reply Position

Etc. The parties need not include any general summaries of the law relating to claim construction. If there are any materials that would be submitted in an appendix, the parties shall submit them in a Joint Appendix.

8. Hearing on Claim Construction. Beginning at 9:00 a.m. on date on or after June 25, 2024, the Court will hear argument on claim construction. Absent prior approval of the Court (which, if it is sought, must be done so by joint letter submission no later than the date on which

The representative claims and the agreed-upon claim constructions do not count against the word limits.

answering claim construction briefs are due), the parties shall not present testimony at the argument, and the argument shall not exceed a total of three hours. When the Joint Claim Construction Brief is filed, the parties shall simultaneously file a motion requesting the above-scheduled claim construction hearing, state that the briefing is complete, and state how much total time the parties are requesting that the Court should allow for the argument.

9. Disclosure of Expert Testimony.

a. Expert Reports. For the party who has the initial burden of proof on the subject matter, the initial Federal Rule 26(a)(2) disclosure of expert testimony is due on or before August 14, 2024. The supplemental disclosure to contradict or rebut evidence on the same matter identified by another party is due on or before September 25, 2024. Reply expert reports from the party with the initial burden of proof are due on or before October 23, 2024. No other expert reports will be permitted without either the consent of all parties or leave of the Court. If any party believes that an expert report does not comply with the rules relating to timely disclosure or exceeds the scope of what is permitted in that expert report, the complaining party must notify the offending party within one week of the submission of the expert report. The parties are expected to promptly try to resolve any such disputes, and, when they cannot reasonably be resolved, use the Court's Discovery Dispute Procedure or the complaint will be waived.

Along with the submissions of the expert reports, the parties shall advise of the dates and times of their experts' availability for deposition. Depositions of experts shall be completed on or before November 20, 2024.

b. Objections to Expert Testimony. To the extent any objection to expert testimony is made pursuant to the principles announced in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), as incorporated in Federal Rule of Evidence 702, it shall be made by motion

no later than the deadline for dispositive motions set forth herein, unless otherwise ordered by the Court.

10. Case Dispositive Motions. All case dispositive motions shall be served and filed on or before December 20, 2024. Responsive briefs shall be served and filed on or before January 17, 2025. Reply briefs shall be served and filed on or before February 7, 2025. No case dispositive motion under Rule 56 may be filed more than ten days before the above date without leave of the Court. Absent an order of the Court upon a showing of good cause, each side is limited to one forty-page opening brief, one forty-page answering brief, and one twenty-page reply brief for all of its Daubert and case dispositive motions.

11. Applications by Motion. Except as otherwise specified herein, any application to the Court shall be by written motion. Any non-dispositive motion should contain the statement required by Local Rule 7.1.1.

12. Pretrial Conference. On date on or after May 16, 2025, the Court will hold a Rule 16(e) final pretrial conference in Court with counsel beginning at 9:00 a.m. The parties shall file a joint proposed final pretrial order in compliance with Local Rule 16.3(c) no later than 5 p.m. on the fourth business day before the date of the final pretrial conference. Unless otherwise ordered by the Court, the parties shall comply with the timeframes set forth in Local Rule 16.3(d) for the preparation of the proposed joint final pretrial order.

13. Motions *in Limine*. Motions *in limine* shall be separately filed, with each motion containing all the argument described below in one filing for each motion. Any supporting documents in connection with a motion *in limine* shall be filed in one filing separate from the motion *in limine*. Each party shall be limited to three *in limine* requests, unless otherwise permitted by the Court. The *in limine* request and any response shall contain the authorities relied upon; each

in limine request may be supported by a maximum of three pages of argument and may be opposed by a maximum of three pages of argument, and the party making the *in limine* request may add a maximum of one additional page in reply in support of its request. If more than one party is supporting or opposing an *in limine* request, such support or opposition shall be combined in a single three page submission (and, if the moving party, a single one page reply). No separate briefing shall be submitted on *in limine* requests, unless otherwise permitted by the Court.

14. Jury Instructions, Voir Dire, and Special Verdict Forms. Where a case is to be tried to a jury, pursuant to Local Rules 47.1(a)(2) and 51.1, the parties should file (i) proposed voir dire, (ii) preliminary jury instructions, (iii) final jury instructions, and (iv) special verdict forms no later than 6 p.m. on the fourth business day before the date of the final pretrial conference. Areas of dispute shall be identified as narrowly as possible and in a manner that makes it readily apparent what the dispute is. The parties shall submit simultaneously with filing each of the foregoing four documents in Word format to rga_civil@ded.uscourts.gov.

15. Trial. This matter is scheduled for a five (5) day jury trial beginning at 9:30 a.m. date on or after June 2, 2025, with the subsequent trial days beginning at 9:30 a.m. Until the case is submitted to the jury for deliberations, the jury will be excused each day at 5:00 p.m. The trial will be timed, as counsel will be allocated a total number of hours in which to present their respective cases.

16. Discovery Referral. This matter is referred to Magistrate Judge Hatcher to handle all discovery disputes including any that arise in connection with expert reports.

17. Mediation (for use in non-ANDA patent cases). The Parties are required to engage in good faith in an in-person mediation. They are to hire a jointly agreed-upon mediator. The timing of mediation efforts is left to the discretion of the Parties, but the mediation efforts need to be

conducted in advance of the pretrial conference. The Parties are required to submit a joint statement no later than one week before the pretrial conference. The joint statement is to include the identification of the mediator, the lead counsel for each party at the mediation, the length of the mediation, and the certification of the lead mediation counsel that they have engaged in the efforts in good faith. If the Parties anticipate any further efforts by the mediator at the time of the submission, they should so advise. The joint statement should not disclose the substance of any offers, counter-offers, or other negotiations.

/s/ Richard G. Andrews

UNITED STATES DISTRICT JUDGE